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EXAMINER	
WEISS JR, JOSEPH FRANCIS	

ART UNIT	PAPER NUMBER
3743	6

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,965	MARTIN ET AL.	
	Examiner	Art Unit	
	Joseph F Weiss Jr.	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-52 and 54-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-52, 54-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 recites the limitation "the other layer" in the last line. There is insufficient antecedent basis for this limitation in the claim.

2. Claim 45 recites the limitation "the other layer" in the last line. There is insufficient antecedent basis for this limitation in the claim.

In regards to claim 57 is the mega Pascal range of 0.15-10 the range or is it just a preference?

3. Claims 71-78 recites the limitation "the pressure drop" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 85-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Gies et al (US 5355910) .

In regards to claim 85, Gies discloses a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat when the valve is in a closed position and such that the flap can flex away from the seal surface when an exhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers is stiffer than the other (See abstract).

In regards to claim 86, Gies discloses the first layer (24) is disposed closer to the seal surface and than the second layer when the valve is closed and wherein the second layer (40) is stiffer than the first layer.

In regards to claim 87, Gies discloses a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat when the valve is in a closed position and such that the flap can flex away from the seal surface when an exhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers has a greater modulus of elasticity than the other (See abstract).

In regards to claim 88, Gies discloses the first layer (24) is disposed closer to the seal surface than the second layer when the valve is closed and wherein the second layer (40) has a greater modulus of elasticity than the first layer.

In regards to claim 89, Gies discloses a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat

when the valve is in a closed position and such that the flap can flex away from the seal surface when an inhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers is stiffer than the other (See abstract).

In regards to claim 90, Gies discloses the first layer (24) is disposed closer to the seal surface and than the second layer when the valve is closed and wherein the second layer (40) is stiffer than the first layer.

In regards to claim 91, Gies discloses a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat when the valve is in a closed position and such that the flap can flex away from the seal surface when an inhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers has a greater modulus of elasticity than the other (See abstract).

In regards to claim 92, Gies discloses the first layer (24) is disposed closer to the seal surface than the second layer when the valve is closed and wherein the second layer (40) has a greater modulus of elasticity than the first layer.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-9, 13-35, 40-52, 56-78, 83-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japuntich et al. (US 5325892) in view of Gies.

In regards to claim 1, Japuntich substantially discloses the instant application's claimed invention to include a mask body (12) adapted to fit over at least the nose & mouth of a wearer to create an interior gas space when worn and an exhalation valve (14) that is in fluid communication with the interior gas space, but does not explicitly disclose the detailed structure of the valve as set forth in the claim . However, Gies disclose a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat when the valve is in a closed position and such that the flap can flex away from the seal surface when an exhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers is stiffer than the other (See abstract). The references are analogous since they are from the same field of endeavor, the respiratory arts (Note the background of Gies teaching the use of the valve for proper ventilation/respiration of passenger compartments of vehicles) and same problem solving area, fluid handling. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gies and used them with the device of Japuntich. The suggestion/motivation for doing so would have been to provide for a more effective valve operation to achieve the objects of invention contemplated by Japuntich (See Summary of the invention) which Gies stipulates such types of operable features are in accord with and more effectively/reliably obtainable via his reed valve structure (summary of invention, note recitations of enhanced seal characteristics, control of flow and operation of the valve). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art as a "reed valve", and one of skill in the art would consider such to amount to a matter of mere

obvious and routine choice of design in the form of interchangeable mechanical equivalency, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 2, the suggested device the first and second layers comprising first and second materials and respectively each having a different modulus of elasticity (note Gies disclosure of layer 24 being a soft flexible elastomer & layer 40 being a rigid plastic).

In regards to claim 3, the suggested device discloses the first layer (24) as closer to the seal surface than the second layer when the flap is positioned against the seal surface and wherein the second layer (40) has a greater MOE than the first layer.

In regards to claim 4, the suggested device discloses the first layer contacts the seal surface when the flap is positioned against the seal surface. (See Gies)

In regards to claim 5, the suggested device discloses the exhalation valve mounted to the mask body (See Japuntich, fig 1).

In regards to claim 6, the suggested device discloses a negative pressure half mask that has a fluid permeable mask body that contains a layer of filter material. (See fig 1 & supporting text).

In regards to claim 7, the suggested device discloses the exhalation valve as a flapper style exhalation valve.

In regards to claim 8, the suggested device discloses the flapper style valve as having a planar surface.

In regards to claim 9, the suggested device is fully capable of having the flexible flap as not being "pressed" against the seal surface under neutral conditions.

In regards to claim 13, the suggested device discloses the second layer having a modulus of elasticity that is greater than the first layer and wherein the first layer contacts the seal surface when the flap is positioned against the seal surface. (See Gies)

In regards to claims 14-19, the suggested device discloses the first layer having an MOE (Modulus of elasticity) that is lower relative to the MOE of the second layer but does not disclose the specific MOEs as set forth by applicant nor the MOE ratios between the layers as set forth by applicant.

It is noted that applicant's specification does not set forth these MOE values or ratios, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 20-25, the suggested device discloses the first and second layers of the flap as having thickness but does not disclose the specific thicknesses as set forth by applicant in claims 20-25.

It is noted that applicant's specification does not set forth these thicknesses, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 26-28 & 33-34, the suggested device discloses a pressure drop of less than 24.5 Pascal at flow levels above 40 liters per min & at 85 liters per minute. (See col 4 lines 4-10 & see example 4 of Japuntich).

In regards to claims 29-32 & 35, the suggested device discloses all the structure of the instantly claimed invention but does not set forth the intended pressure drop results as set forth by applicant at flow rate of 10 liters per minute. However one of ordinary skill would consider

the suggested device as being fully capable of demonstrating the same pressure drop results at this same flow level because it performed in the same range at the other set forth flow rates and because it possesses all the structure applicant has set forth as necessary to perform under these given test conditions.

Accordingly, one of ordinary skill in the art would consider such to not constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 40, the suggested device discloses the first and second layers of materials being made out of polymeric materials. (Note Gies disclosure of use of plastics and elastomers and cross hatching of depicted in Gies' figures).

In regards to claim 41, the suggested device discloses use of a rubber in the first layer (note teaching of use of elastomers for layer 24) and the use of rigid materials for the second layer but does not disclose the use of poly-carbonate or polyethylene terephthalate..

It is noted that applicant's specification does not set forth the use of these specific rigid materials, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 42, the suggested device discloses the claimed invention except for the use of styrene-butadiene-styrene block co-polymer for the first layer.

It is noted that applicant's specification does not set forth use of this specific rubber/elastomer, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 43, the references noted above substantially disclose the claimed invention's structure but does not claim the specific valve efficiency value as set forth in the claim.

It is noted that applicant's specification does not set forth this value, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of ordinary skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 44, the references noted above substantially disclose the claimed invention's structure but does not claim the specific valve efficiency value as set forth in the claim.

It is noted that applicant's specification does not set forth this value, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of ordinary skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 45, Japuntich substantially discloses the instant application's claimed invention to include a mask body (12) adapted to fit over at least the nose & mouth of a wearer to create an interior gas space when worn and an exhalation valve (14) that is in fluid communication with the interior gas space, but does not explicitly disclose the detailed structure of the valve as set forth in the claim . However, Gies disclose a valve having a valve seat (20) comprising a seal surface and an orifice through which a fluid may pass (see fig 2), and a flexible flap (22) mounted to the valve seat that is fully capable such that the flap makes contact with the seat when the valve is in a closed position and such that the flap can flex away from the seal surface when an exhale flow stream passes through the valve the flexible flap comprising at least a first and second juxtaposed layers (24 & 40 respectively) wherein one of the layers has a greater modulus of elasticity than the other (See abstract). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gies and used them with the device of Japuntich. The suggestion/motivation for doing so would have been to provide for a more effective valve operation to achieve the objects of invention contemplated by Japuntich (See Summary of the invention) which Gies stipulates such types of operable features are in accord with and more effectively/reliably obtainable via his reed valve structure (summary of invention, note recitations of enhanced seal characteristics, control of flow and operation of the valve). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art as a "reed valve", and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design in the form of interchangeable mechanical equivalency, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 46, the suggested device discloses the first layer (24) as closer to the seal surface than the second layer when the flap is positioned against the seal surface and wherein the second layer (40) has a greater MOE than the first layer.

In regards to claim 47, the suggested device discloses the first layer contacts the seal surface when the flap is positioned against the seal surface. (See Gies)

In regards to claim 48, the suggested device discloses the exhalation valve mounted to the mask body (See Japuntich, fig 1).

In regards to claim 49, the suggested device discloses a negative pressure half mask that has a fluid permeable mask body that contains a layer of filter material. (See fig 1 & supporting text).

In regards to claim 50, the suggested device discloses the exhalation valve as a flapper style exhalation valve.

In regards to claim 51, the suggested device discloses the flapper style valve as having a planar surface.

In regards to claim 52, the suggested device is fully capable of having the flexible flap as not being "pressed" against the seal surface under neutral conditions.

In regards to claim 56, the suggested device discloses the second layer having a modulus of elasticity that is greater than the first layer and wherein the first layer contacts the seal surface when the flap is positioned against the seal surface. (See Gies)

In regards to claims 57-62, the suggested device discloses the first layer having an MOE (Modulus of elasticity) that is lower relative to the MOE of the second layer but does not disclose the specific MOEs as set forth by applicant nor the MOE ratios between the layers as set forth by applicant.

It is noted that applicant's specification does not set forth these MOE values or ratios, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 63-68, the suggested device discloses the first and second layers of the flap as having thickness but does not disclose the specific thicknesses as set forth by applicant in claims 63-68.

It is noted that applicant's specification does not set forth these thicknesses, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 69-71 & 76-77, the suggested device discloses a pressure drop of less than 24.5 Pascal at flow levels above 40 liters per min & at 85 liters per minute. (See col 4 lines 4-10 & see example 4 of Japuntich).

In regards to claims 72-75 & 78, the suggested device discloses all the structure of the instantly claimed invention but does not set forth the intended pressure drop results as set forth by applicant at flow rate of 10 liters per minute. However one of ordinary skill would consider the suggested device as being fully capable of demonstrating the same pressure drop results at this same flow level because it performed in the same range at the other set forth flow rates and because it possesses all the structure applicant has set forth as necessary to perform under these given test conditions.

Accordingly, one of ordinary skill in the art would consider such to not constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 83, the references noted above substantially disclose the claimed invention's structure but does not claim the specific valve efficiency value as set forth in the claim.

It is noted that applicant's specification does not set forth this value, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of ordinary skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 84, the references noted above substantially disclose the claimed invention's structure but does not claim the specific valve efficiency value as set forth in the claim.

It is noted that applicant's specification does not set forth this value, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of ordinary skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

8. Claims 11-12, 36-37, 54-55 & 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japuntich & Gies as applied to claims 1 & 45 above, and further in view of Herlihy (US 5285816).

In regards to claims 11 & 54 the suggested device discloses the instant application's claimed invention, but does not explicitly disclose the use of a third layer that has substantially the same stiffness as the first layer. However, Herlihy disclose such (see figs 1, 3, 7-8 and supporting text). The references are analogous since they are from the same field of endeavor, the fluid handling/valving arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Herlihy and used them with the suggested device. The suggestion/motivation for doing so would have been to optimize actuation of the valve by having an elastomeric bilayer serve as the hinge without use/interference by the stiffer/more rigid layer . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 12, 55 the suggested device discloses a symmetric flexible flap w/ respect to the second layer and wherein the second layer is stiffer than the first & third layers. (See Herlihy)

In regards to claim 36, 79, the suggested device discloses an ABA structure wherein layer B is stiffer than the A layers.

In regards to claim 37, 80 the suggested device discloses ABA' structure wherein layer B is stiffer than the A & A' layers and the A layer is located closer to the seal surface than the B layer.

9. Claims 38-39 & 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japuntich & Gies as applied to claims 1 & 45 above, and further in view of Airhart (US 3994319).

In regards to claims 38-39 & 81-82 the suggested device discloses the instant application's claimed invention, but does not explicitly disclose the use of a third distinct or "C" layer and in regards to claims 39 & 81 is stiffer that the A or B layers & is located closer to the seal surface than the A and B layers. However, Airhart disclose such (note how subsequent layers reinforce the layer that contacts the sealing surface). The references are analogous since they are from the same field of endeavor, the fluid handling/valving arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Airhart and used them with the suggested device. The suggestion/motivation for doing so would have been to reduce elasticity to optimize actuation of the valve using a more rigidly layered flap valve element . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

10. Claims 93 & 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gies et al as applied to claims 89 & 91 respectively above, and further in view of Shigematsu et al (US 5829433).

In regards to claim 93, Gies substantially discloses the instant application's claimed invention, but does not explicitly disclose use of the valve in a filter mask for controlling inspiration. However, Shigrematsu disclose such an arrangement (see valve 25 & supporting text). The references are analogous since they are from the same field of endeavor, the

respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Shigematsu and used them with the device of Gies. The suggestion/motivation for doing so would have been because Shigematsu discloses the combination of a valve for controlling inhalation with a valve in a filter mask and Gies discloses the subcombination of a valve that is fully capable of controlling inhalation . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 94, Gies substantially discloses the instant application's claimed invention, but does not explicitly disclose use of the valve in a filter mask for controlling inspiration. However, Shigermatsu disclose such an arrangement (see valve 25 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Shigematsu and used them with the device of Gies. The suggestion/motivation for doing so would have been because Shigematsu discloses the combination of a valve for controlling inhalation with a valve in a filter mask and Gies discloses the subcombination of a valve that is fully capable of controlling inhalation . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

3. Claims 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japuntich & Gies as applied to claims 1 & 45 above, and further in view of Airhart (US 3983900).

Japuntich & Gies substantially discloses the instant application's claimed invention, but does not explicitly disclose the two layers laminated at the point of where the flap bends as set forth in claims 95-98. However, Airhart disclose such (note illustrations of contiguous integrity running the enter length of the reed to include the flap bending point. The references are analogous since they are from the same problem solving area, fluid flow handling/management. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Airhart and used them with the suggested device. The suggestion/motivation for doing so would have been to provide for a more resilient and responsive valving and handling of fluid flow. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

1. Applicant's arguments with respect to claims 1-9, 11-52, 54-94 have been considered but are moot in view of the new ground(s) of rejection.

In regards to the objection to the drawings, the amendment is proper and responsive and resolves the issue, thus the objection is withdrawn.

In regards to the rejections to the claims under 35 USC 112, the amendment is partially proper and responsive and resolves some of the issue, thus the rejections have been partially withdrawn, those retained must be addressed.

In regards to the 35 USC 102 rejection applicant's conclusory statement that by using the labels "inhalation" and "exhalation" that the same structure disclosed by the prior art now becomes patently distinct. The examiner finds no evidence or legal precedence to come to such a conclusion. Gies discloses all of the positively claimed structural limitations that applicant has set forth, thus the rejections are retained. And contrary precedent regarding such pre-amble limitations does exist:

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

On motivations to combine, please read the rejection and note the following:

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves **or in the knowledge generally available to one of ordinary skill in the art.** See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In regards to the references not being analogous please read the rejection and note the following:

In response to applicant's argument that Gies & the other references used is nonanalogous art, it has been held that a prior art reference must either be **in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned,** in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gies expressly teaches the use of the valve for ventilation in the passenger compartment of vehicles, hence its in the respiratory arts. Furthermore, its in the same problem solving area, fluid handling. Finally, a valve is a valve is a valve, whether its classified in 137 fluid handling or 128 respiration.

On evidence/burden of proof, contrary to applicant's conclusory pronouncement that insufficient evidence has been presented to shift the burden of proof, the examiner finds the contrary. Sufficient evidence has been presented on the record as a whole, as VIEWED BY ONE OF ORDINARY SKILL IN THE RELEVANT ART and a reasoned basis in accordance with 5 APA 555 based upon such evidence was presented to applicant which reached the sound conclusion that the claims as currently set forth are anticipated/obvious and hence unpatentable in their current state. On the contrary

applicant has failed to respond to the office action that properly and fully shifted the burden to applicant. (Please produce legally binding precedent that stipulates that the common law four corners doctrine of contract law applies to patent prosecution and trumps the ordinary skilled observer standard in evaluation evidence.)

Regarding intended results, uses and purposes for the valves, it is suggested that applicant claim any commensurate structures that facilitates such in order to structurally distinguish over the prior art.

Regarding the differences of the Giles valve in terms of additional features and manner of function, it is noted that applicant uses open claim language and does not have negative limitations regarding such features/functions nor does applicant say anything about the use/affect of gravity on his valve. Thus the arguments are not persuasive.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Aaron J. Lewis
Primary Examiner

JFweiss
12/9/03